REMARKS

Claims 1-5 and 16-29 were pending in this application. Claim 1 has been amended. No claims have been canceled. No new claims have been added.

Claim 1 has been amended to include a step (a) of selecting a peptide from an allergen for its ability to induce a late phase reaction. Support for this amendment may be found throughout the specification and claims as originally filed, and at least on page 23, lines 21-28 and page 47, lines 22-24. Claim 1 has also been amended to specify that the selected peptide is derived from one of the specific polypeptide allergens represented by SEQ ID NO's: 19-31, 35, 36, 38-86 and 88-124. Support for this amendment may be found throughout the specification and claims as originally filed, and at least on page 50, line 2 through page 81, line 2 of the specification, which describes the use of these allergen sequences in the selection of peptides for the methods as claimed. Applicants submit that no new matter has been added.

Withdrawal of Certain Rejections

Applicants acknowledge the withdrawal of the rejection of claims 1-5 under 35 U.S.C. 102(b) in view of Tovey *et al.*

Foreign Priority

Applicants thank the Examiner for acknowledging the claim for foreign priority. The Examiner has noted that certified copies of the United Kingdom 9800445.0 and 9820474.6 applications have not been filed as required by 35 U.S.C. 119(b). Applicants hereby submit electronic versions of the certified UK priority applications obtained from the EPO registry, as submitted in the International Phase. These electronic versions of 9800445.0 and 9820474.6 are believed to fulfill the requirements of 35 U.S.C. 119(b)(3).

Claims 1-5 are Rejected Under 35 U.S.C. § 112, 1st paragraph

Enablement

The Examiner has maintained the rejection of claims 1-5 under 35 U.S.C. 112, 1st paragraph, on the grounds that they allegedly fail to comply with the enablement requirement.

Specifically, the Examiner has stated that it is not "routine experimentation to determine the MHC restriction of every peptide of 5-50 amino acids of any known, unknown, or variant allergen from grass, tree and weed pollens..." The Examiner further stated that "[a]pplicant's assertion that the claims only encompass 'isolated peptides from known allergens having defined functional and structural features' is not accurate" in large part because the "recitation [of allergens] includes variant allergens from any of those allergen sources." Applicants respectfully traverse the Examiner's rejection.

Applicants respectfully disagree with the Examiner's position with regard to the instant enablement rejection for the reasons of record previously stated in the Response filed February 20, 2009. However, in order to expedite the allowance of this application, and not in acquiescence to the Examiner's rejection, Applicants have amended claim 1 to further clarify that the invention is directed to the use of specific polypeptide allergens "selected from the group consisting of SEQ ID NO's: 19-31, 35, 36, 38-86 and 88-124." In view of this amendment, Applicants respectfully submit that the person of skill in the art is provided with specific polypeptide sequence information that can be used to select peptides of the desired length and with the desired properties. As previously described in our Response filed on February 20, 2009, the generation of peptides from protein sequences and their testing to identify the desired function of binding to a particular MHC Class II is well known in the art, and does not constitute an undue burden.

Additionally, Applicants note that claim 1 has also been amended to include a step (a) of selecting a peptide from an allergen for its ability to "induce a late phase reaction..." which further clarifies the method of the invention. Specifically, this amendment clearly directs a person skilled in the art as to how to make the claimed peptides for use in inhibiting an allergic reaction. Methods of testing peptides for their ability to induce a late phase reaction are known in the art, as evidenced by the documents submitted with the Response filed on February 20, 2009.

Furthermore, the specification provides a detailed teaching in relation to the particular methods as claimed in instant amended claim 1, which includes combined steps of selecting peptides based on an ability to induce a late phase reaction, and their administration to inhibit an allergic reaction. An important technical teaching of the invention is that peptides having the ability to induce a late phase reaction are particularly suitable for the inhibition of allergic reactions. In particular, Examples 2 to 4 at page 42, line 16 to page 46, line 7 teach the selection

of SEQ ID NOs 1 to 3 based on their ability to induce a late phase reaction. Example 7 at page 85, line 24 to page 89, line 13 is a working example demonstrating the use of such peptides in inhibiting allergic reactions. The specification also provides a detailed experimental disclosure in relation to how peptides from other allergens could be selected and used according to the invention (see e.g. Example 6, page 47, line 22 to page 85, line 22).

Applicants further submit that any unpredictability in the art cited by the Examiner is addressed by the amendments made to claim 1. The claims include a step of selecting peptides for their ability to induce a late phase reaction, and the specification provides working examples that demonstrate that peptides having this property are suitable for inhibiting allergic reactions. Therefore the methods are limited to the identification and use of peptides which would predictably inhibit allergic reactions. The Applicant has provided a teaching as to how any unpredictability in the use of peptides for inhibition of allergic reactions can be addressed. This is reflected in the claims in the particular step of selecting peptides for their ability to induce a late phase reaction.

Similarly, there is no lack of enablement related to the use of altered peptides. Any altered peptides that are not able to induce a late phase reaction would not be selected for use in the methods as claimed, which require that the subject peptides have this property. In addition, the Declaration previously filed by Dr Mark Larche described that the teaching of Kinnunen *et al.* in relation to autoimmune disease was not predictive of an unsuitability for altered peptides in treatment of allergic reactions.

Applicants respectfully submit that the amended claims are enabled by the teachings of the specification. The selection and use of appropriate peptides would be well within the ability of a person skilled in the art, taking into account the level of knowledge of one of skill in the art, in combination with the extensive guidance provided by the specification as to the selection and use of peptides derived from the specific peptide allergen sequences claimed to inhibit allergic reactions.

Written Description

The Examiner has further rejected claims 1-5 under 35 U.S.C. 112, 1st paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the

application was filed, had possession of the claimed invention for the same reasons as set forth in the Office action mailed on 03/28/2007. Applicants respectfully traverse the rejection.

The Examiner has maintained that the specification does not show that the inventors possessed the invention at the time of filing, in particular due to the lack of an adequate correlation between function and structure. As discussed above, Claim 1 has been amended to disclose that the selected peptide is derived from a discrete number of defined polypeptide allergens comprising an amino acid sequence selected from the group consisting of SEQ ID NO's: 19-31, 35, 36, 38-86 and 88-124. Applicants respectfully submit that the genus of peptides claimed for use is now limited to those of a defined length selected from a defined list of allergen sequences. The specification at page 50, line 2 to page 81, line 2 clearly describes this genus and so provides an adequate disclosure of the structural properties of the peptides.

Furthermore, the specification also teaches how peptides of this structural genus may be correlated with the function of inducing a late phase reaction and used to inhibit allergic reactions. The specification in particular provides a description of how peptides selected structurally from allergen proteins may be tested to identify those able to induce a late phase reaction (Example 6, as discussed above). Applicants respectfully submit that this teaching clearly indicates that Applicants were in possession of the claimed genus at the time of filing. The necessary correlation between structure and function required to adequately describe the genus is provided by the specific peptide allergen sequences recited in the claims and the functional language with respect to late phase reactions. As discussed above, the Examples show that peptide sequences from allergen sequences which have been selected in this manner are able to inhibit allergic reactions.

The Examiner also commented that the disclosure of the necessary screening method did not necessarily lead to the genus of peptides. In particular, the case of *Univ. Of Rochester V.G.D Searle & Co., Inc.,* 358F.3d916, 69 USPQ2d 1886 (fed.Cir.2004) is highlighted. An important distinction over the facts of that case is that the present invention does provide a working example in which peptides (SEQ ID NOs: 1 to 3) possessing the claimed structure and function are demonstrated to inhibit allergic reactions.

The present application does not, therefore, merely disclose assays for screening peptides, but provides specific peptides selected by such assays which are then shown to have the necessary inhibitory property. Applicants submit that this disclosure of specific and concrete

peptides having the same properties as the claimed genus of peptides leads to an adequate written description.

Thus, the teaching provided in the present invention in relation to specific peptides can be distinguished over the situation of *Univ. Of Rochester V.G.D Searle & Co., Inc.,* where no such disclosure of any compounds used in the claimed methods was present. The members of the claimed genus are also not selected at random from a variety of different substances, but have the common feature that they are all peptides of 5 to 50 amino acids in length, able to bind to a particular MHC Class II and being from allergens defined by specific amino acid sequences (i.e. SEQ ID NO's: 19-31, 35, 36, 38-86 and 88-124). Applicants respectfully submit that the exemplification of particular peptides having these features (i.e. SEQ ID NOs 1 to 3) indicates clear possession of the genus of peptides having these features.

Claims 1-5 are Rejected Under 35 U.S.C. § 102(b)

Bungy Poor Fard *et al.*

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bungy Poor Fard *et al.* (PTO-892; Reference U). The Examiner has alleged that Bungy Poor Fard *et al.* teaches method of inhibiting an allergic reaction to rye grass in an individual (Lol p 1 allergic patients) comprising administering to the individual patient a composition comprising an isolated 12 amino acid peptide of Lol p 1 allergen from rye grass (plurality of peptides), wherein the peptide is able to bind a particular restriction to a MHC Class II molecule possessed by the individual (In particular, page 113 'Study of overlapping peptides in vivo' section, Figure 3, whole document). Applicants traverse.

Applicants respectfully disagree with the Examiner's assertion that peptides having the ability to induce a late phase reaction are disclosed in Bungy Poor Fard *et al.* However, in order to expedite the allowance of this application, claim 1 has been amended so that the polypeptide allergen sequences specified for selection of peptides do not include Lol p 1, which is the subject of Bungy Poor Fard *et al.* Consequently, Applicants respectfully submit that this rejection is overcome, and withdrawal is therefore respectfully requested.

Bauer *et al.*

The Examiner has further rejected Claims 1-3 under 35 U.S.C. 102(b) as allegedly being anticipated by Bauer *et al.* (PTO-892; Reference V). Bauer *et al.* teaches method of inhibiting an allergic reaction to birch pollen in an individual (mice) comprising administering to the individual patient (mice) a composition comprising an isolated 14 amino acid peptide of Bet v 1 allergen from birch pollen (plurality of peptides), wherein the peptide is able to bind a particular restriction to a MHC Class II molecule possessed by the individual (In particular, page 537 'Treatment protocol' section, Figures 2 and 5, whole document).

Applicants respectfully disagree with the Examiner's assertion that peptides having the ability to induce a late phase reaction are disclosed in Bauer *et al.* However, in order to expedite the allowance of this application, claim 1 has been amended so that the polypeptide allergen sequences specified for selection of peptides do not include Bet v 1, which is the subject matter of Bauer *et al.* Applicants respectfully submit that this rejection is overcome, and withdrawal is respectfully requested.

Additionally, Applicants submit that the method of instant amended claim 1 is further distinguished from all of the above cited prior art since it requires a step of selecting peptides able to induce a late phase reaction. Neither reference either teaches or suggests selecting peptides having this property for use in inhibiting allergic reactions. The methods of selecting and using the peptides as claimed are therefore novel and non-obvious over the prior art. Applicants respectfully request withdrawal of both rejections issued under 35 U.S.C. 102(b), and respectfully request reconsideration of the pending claims.

CONCLUSION

In view of the amendments and remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney could be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

A Request for the appropriate extension of time is being filed concurrently herewith. With respect to the fee that is due, please charge our Deposit Account No. 12-0080, under Order No. JKJ-005CNRCE, from which the undersigned is authorized to draw.

Dated: December 9, 2009

Respectfully submitted,

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Enclosures